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(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in §414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66402, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

[70 FR 39095, July 6, 2005]

§414.912 Conflicts of interest

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

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(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

[70 FR 39094, July 6, 2005]

§414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in §414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at §414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and

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abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral ("Stark") prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in §414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within

the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in §414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Respond within 2 business days to any inquiry, or sooner if the inquiry is related to drug quality;

(6) Staff a toll-free telephone line from 8:30 a.m. or earlier and until 5 p.m. or later for all time zones served in the continental United States by the CAP vendor on business days (Monday through Friday excluding Federal holidays) to provide customer assistance, and establish reasonable hours of operation for Hawaii, Alaska, Puerto Rico, and the other U.S. territories;

(7) Staff an emergency toll-free telephone line for weekend and evening access when the call center is closed, and determine what hours on Saturday and Sunday the call center is staffed and which hours a toll-free emergency line is activated; and

(8) Include assistance for the disabled, the hearing impaired, and Spanish-speaking inquirers in all customer service operations.

(9) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(10) Be enrolled in Medicare as a participating supplier;

(11) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(12) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of paragraph (h) of this section or §414.916(b) of this subpart are met;

(13) Provide direct notification to participating CAP physicians enrolled with them of updates to the approved

CAP vendor's CAP drug list on a quarterly basis. Changes must be disseminated at least 30 days before the approved changes are due to take effect, unless immediate notification as described in §414.906(f)(4) is required. The approved CAP vendor's entire CAP drug list must be disseminated at least once yearly; and approved CAP vendors must make a complete list that incorporates the most recent updates available to physicians on an ongoing basis. CMS posts on its web site the updated CAP drug lists for each approved CAP vendor.

(14) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(15) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(16) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of "Remuneration" in §1003.101 of this title. The availability of waivers may

not be advertised or be made as part of a solicitation. Approved CAP vendors must inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries receive cost-sharing waivers.

(h) The approved CAP vendor must verify drug administration prior to collection of any applicable cost sharing amount.

(1) The approved CAP vendor documents, in writing, the following information necessary to verify drug administration:

(i) Beneficiary name.

(ii) Health insurance number.

(iii) Expected date of administration.

(iv) Actual date of administration.

(v) Identity of the participating CAP physician.

(vi) Prescription order number.

(vii) Identity of the individuals who supply and receive the information.

(viii) Dosage supplied.

(ix) Dosage administered.

(2) If the information is obtained verbally, the approved CAP vendor must also maintain the following information:

(i) The identities of individuals who exchanged the information.

(ii) The date and time that the information was obtained.

(3) The approved CAP vendor must provide this information to CMS or the beneficiary upon request.

(i) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of payment by Medicare, or the verification of drug administration by the participating CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) An approved CAP vendor that has received payment from the designated carrier for CAP drugs that have not been administered must promptly refund payment for such drugs to the designated carrier and must refund any

coinsurance and deductible collected from the beneficiary and his or her supplemental insurer.

(3) At the time of billing the beneficiary, or the participating CAP physician's presentation of the bill on behalf of the approved CAP vendor, the approved CAP vendor must inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and §414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) For purposes of paragraph (i) of this section delivery means postmark date, or the date the coinsurance bill or notice was presented to the beneficiary by the participating CAP physician on behalf of the approved CAP vendor.

(i) Except as specified in paragraph (i)(5)(ii) of this section, if after 45 days from delivery of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost-sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary.

(ii) If the beneficiary has requested cost-sharing assistance within 45 days of receiving delivery of the approved CAP vendor's bill, provisions of paragraphs (i)(6), (i)(7), or (i)(8) of this section, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in §414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the delivery of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and §414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with

§414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the date of delivery of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

[70 FR 39096, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in §414.908(a)(3). The recommendation will include numbered findings of fact.